

ACCOMPANYING LABELING: Leaflets entitled "For Radiant Health Use Torulose" and "JerOtene Organic Carotene A Capsules"; also additional bottle labels for *Torulose tablets* and *JerOtene capsules*.

RESULTS OF INVESTIGATION: The *Torulose tablets and powder* in the bottles and cans were shipped in bulk and repacked and labeled by the dealer and, in the ordinary course of the dealer's business, the *JerOtene capsules* in the box were to be repacked into bottles labeled as described above.

LIBELED: 6-29-61, W. Dist. Mich.; amended libel filed 7-7-61.

CHARGE: *Torulose tablets and powder*, 502(a)—while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective to promote radiant health and to promote the development of champions.

*JerOtene capsules*, 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to promote growth, appetite and digestion; maintain a healthy appearance of hair and fingernails; maintain healthy balance of epithelial and nerve tissues; and to prevent infection of the respiratory system.

The libel alleged also that the *Torulose tablets and powder* and another article were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7-11-61. Consent—claimed by the dealer and released under bond for relabeling.

6694. **Sacro-Disc-30.** (F.D.C. No. 44926. S. No. 4-563 R.)

QUANTITY: 346 100-tablet btl. at Baltimore, Md., in possession of Armisyl Products Co.

SHIPPED: 5-27-60, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Sacro-Disc-30 Aneurine HCl 100 mg. U.S.P. Dose: 3 Tablets Daily \* \* \* 12471 Distributed by Armisyl Products, 2806 W. Strathmore Ave. Baltimore 9, Md."

ACCOMPANYING LABELING: Brochures entitled "Suffering from Backache? Leg Pain?"

RESULTS OF INVESTIGATION: The article was repacked by the Barre Drug Co., Inc., Baltimore, Md., after shipment as described above. The bottles and labels for use in repacking the article were supplied by the Armisyl Products Co. The above-mentioned brochures were prepared locally for the Armisyl Products Co. Analysis showed that the article contained thiamine hydrochloride.

LIBELED: 10-3-60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name "Sacro-Disc-30" and statements in the accompanying labeling of the article represented and suggested that the article was an adequate and effective treatment for backaches, leg pains, slipped disc, pains in general, arthritis, rheumatism, stiff joints, sleeplessness, nervous disorders, such as memory defects, depression, and severe agitation, and that the article was essential both to fertility and growth, and important to nerves, appetite, and digestion, which name and statements were false and misleading since the article was not an adequate and effective treatment for such conditions and purposes and was not capable of fulfilling the promises of benefit made for it; and 502(e) (2)—

the label of the article failed to bear the common or usual name of each active ingredient contained therein, namely, thiamine hydrochloride.

DISPOSITION: 8-2-61. Consent—destruction.

**6695. Propa-Vite capsules.** (F.D.C. No. 44365. S. No. 50-064 P.)

QUANTITY: 10 btl., each containing 1,000 capsules, at Evansville, Ind.

SHIPPED: 1-31-58, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: (Btl.) "Propa-Vite Capsules Each capsule contains: Phenylpropanolamine hydrochloride 25 mgm. Methylcellulose 100 mgm. Vitamin A Acetate 1000 USP Units Vitamin D (Calciferol) 100 USP Units Thiamin Chloride 2 mgm. Riboflavin 1 mgm. Pyridoxine HCl 0.1 mgm. Niacinamide 10 mgm. Folic Acid 0.1 mgm. Vitamin B-12 (cobalamin conc.) 0.5 mcgm. Ascorbic Acid 10 mgm. Iron (from ferrous sulfate) 3 mgm. Calcium (from dicalcium phosphate) 50 mgm. Phosphorous (from dicalcium phosphate) 37.5 mgm. Iodine (from Potassium Iodide) 0.5 mgm. Fluorine (from calcium fluoride) 0.05 mgm. Copper (from copper sulfate) 1 mgm. Potassium (from potassium sulfate) 5 mgm. Manganese (from manganese sulfate) 1 mgm. Zinc (from zinc sulfate) 0.01 mgm. Magnesium (from magnesium sulfate) 1 mgm. Boron (from sodium borate) 0.05 mgm. \* \* \* Nysco Laboratories, Inc. \* \* \* Long Island City, N.Y."

LIBELED: On or about 3-21-60, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the label statement "For use as an aid in reducing diets as an appetite depressant" was false and misleading since the article was not effective for this purpose.

DISPOSITION: 5-18-60. Default—destruction.

**6696. Leah's Delicious Diet with Ease.** (F.D.C. No. 45727. S. No. 50-287 R.)

QUANTITY: 206 btl., each containing 100 wafers, at Denver, Colo.

SHIPPED: 2-16-61, from New York, N.Y., by Approved Formulas, Inc.

LABEL IN PART: (Btl.) "Leah's Delicious Diet with Ease Food Supplement For Appetite Control The Natural Way Safe - Sane - Simple \* \* \* Distributed by Leah's Foods, Aurora, Colo. No Drugs - No Tricks Really stems hunger like a meal - by providing nourishing protein. Only 4 calories per wafer. Children or Adults Chew or swallow 2 or 3 tasty wafers before meals or whenever hungry. Percent of Essential Amino Acids in each tablet: Arginine 3.34 \* \* \* Each 16 grains contain: Protein 75% Fat 1.4% Carbohydrate 14% 11357."

LIBELED: 4-19-61, Dist. Colo.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was as adequate and effective to control appetite and to stem hunger as a meal would be.

The libel alleged also that the article was misbranded under the provisions of the Act relating to foods as reported in notices of judgment on foods.

DISPOSITION: 6-7-61. Default—destruction.

**6697. Oxy-Aid oxygen inhalator.** (F.D.C. No. 45720. S. No. 57-225 R.)

QUANTITY: 258 devices at New York, N.Y., in the possession of Oxy-Aid Scientific Corp.

SHIPPED: Between 2-1-58 and 3-31-58, from Chicago, Ill., by Emergency Medical Oxygen Co., Inc.